

Appl. No. 09/811,360  
Amendment dated October 6, 2005  
Reply to Office Action mailed May 12, 2005

Attorney Docket No. 355004-991501

## **REMARKS/ARGUMENTS**

### **Remarks**

Claims 1, 4-6, 8-25, 28-43, 50-52 and 54-55 are pending in this application. Claim 25 is currently amended for an informality.

### **Claim Objections**

Claim 25 has been amended to correct the informality raised by the Examiner, and the objection is thereby overcome.

### **Claim Rejections Under 35 U.S.C. 103**

Claims 1, 4-6, 8-25, 28-39, 41-43, 50-52, 54 and 55 are rejected under 35 U.S.C. 103 as being unpatentable over U.S. patents 4,550,450 to Kinnett, 5,326,366 to Pascarella et al., 4,042,980 to Swanson et al., and German patent DE 1164019 to Chiron-Werke. Each of these claims, as previously amended, is allowable because there is no suggestion or motivation to combine these references because Pascarella et al. represents non-analogous prior art.

Pascarella et al. specifically relates to a biomechanical implant for re-surfacing a damaged phalanx of a human big toe. The present invention, by contrast, specifically relates to total shoulder arthroplasty. Not only is the human shoulder joint vastly different both geometrically and bio-mechanically to the proximal phalanx of the human big toe, but each of these areas of human physiology represent entirely separate medical specialties.

Orthopedic surgeons in general orthopedic practice are inexperienced in total shoulder arthroplasty and typically refer such cases to shoulder specialists when a shoulder arthroplasty is necessary. Indeed, many primary care physicians do not even know that a prosthetic total shoulder arthroplasty exists

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as an option for their patients. Similarly, the joint of the big toe represents its own completely separate and unrelated area of orthopedic specialty.

As evidence of the separate and non-overlapping nature of the medical fields concerned with these very different joints of the human body, enclosed is a copy of two separate Declarations. One of these is a Declaration of Dr. Eugene M. Wolf, and expert in shoulder replacement surgery and the inventor and applicant for the present application. The other is a Declaration by Dr. Glenn B. Pfeffer, an expert in foot and ankle surgery and big toe implant surgery.

As is clear from the Declarations, the two fields of medical endeavor concerned are generally non-overlapping. Accordingly, it is quite unreasonable to suggest that a person skilled in the field of total shoulder arthroplasty would look to big toe implant resources to seek new techniques or developments that may be applicable in the shoulder joint. As stated above, the joints are entirely dissimilar, not only in size but also in their geometry and their bio-mechanical structure. It is therefore entirely unreasonable to suggest that the present invention would have been obvious to a person skilled in the art of total shoulder arthroplasty having Kinnett, and then considering that disclosure in combination with Pascarella et al. Pascarella et al. would simply not have been taken into consideration at all.

Accordingly, it is respectfully submitted that the Examiner's rejection under 35 USC 103(a) based on a combination of Kinnett and Pascarella should be withdrawn, and Applicant's claims deemed allowable.

It is respectfully submitted that the application is now in condition for allowance. The Examiner's early reconsideration is respectfully requested.

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The Commissioner is authorized to charge any deficiencies in fees and credit any overpayment of fees to Deposit Account No. 07-1896. A duplicate page is enclosed.

Respectfully submitted,

DLA PIPER RUDNICK GRAY CARY US LLP

Dated: 10-6-05

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**DUPLICATE**

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Respectfully submitted,

DLA PIPER RUDNICK GRAY CARY US LLP

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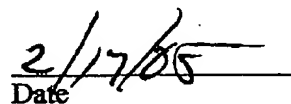
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DECLARATION OF DR. EUGENE M. WOLF

I, Dr. Eugene M. Wolf, of 55 Montacito Road, San Rafael, California, hereby declare that I received a M.D. from The Universite de Bordeaux in France and have been practicing shoulder replacement surgery for 20 years. I am extensively familiar with this medical field. I also have many colleagues that practice big toe implant surgery including Dr. Glen Pfeffer. A big toe implant surgery is a vastly different procedure than a shoulder replacement due to differences in the anatomy of the joint involved. Specifically, they are different joints with different biomechanics and different surgical approaches. As a result, there are doctors who specialize in the field of foot and ankle surgery performing big toe implants and those who specialize in the field of shoulder surgery who perform total shoulder arthroplasty, and these groups of medical professionals are generally non-overlapping.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

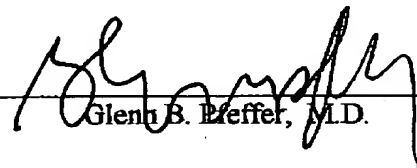
  
Eugene M. Wolf, M.D.

  
Date

DECLARATION OF DR. GLENN B. PFEFFER

I, Dr. Glenn B. Pfeffer, of 3000 California Street, San Francisco, California, hereby declare that I received a M.D. from University of Pennsylvania in 1980 and have been practicing Foot and Ankle Surgery and big toe implant surgery for 15 years. I am extensively familiar with this medical field. I also have many colleagues that practice shoulder replacement surgery including Dr. Eugene M. Wolf. I agree with Dr. Wolf that a big toe implant surgery is a vastly different procedure than a shoulder replacement due to differences in the joint involved. As Dr. Wolf has stated, they are different joints with different biomechanics and different surgical approaches. As Dr. Wolf noted, the anatomy and surgical approaches of the joint of the big toe and the shoulder are very different. As a result, I agree with Dr. Wolf that there are doctors who specialize in the field of big toe implant surgery and those who specialize in the field of shoulder replacement surgery, and these groups of medical professionals are generally non-overlapping.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made upon information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment or both under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

  
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Glenn B. Pfeffer, M.D.

2/18/05  
Date